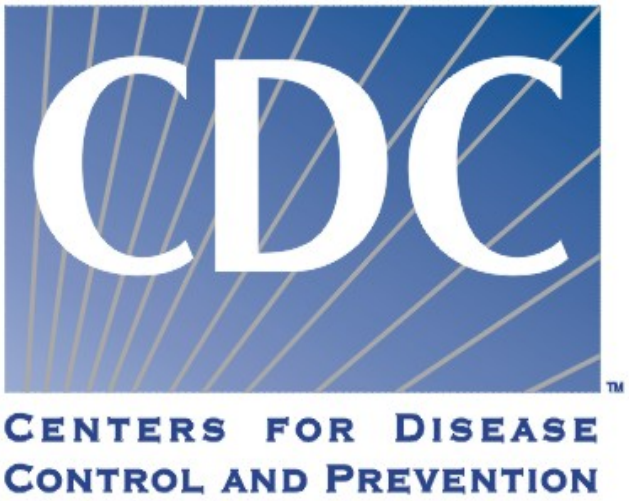
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Infectious Diseases
Division of Healthcare Quality Promotion



Healthcare Infection Control Practices Advisory Committee
October 24-25, 2005
Atlanta, Georgia

Record of the Proceedings

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ATTACHMENT 1

List of Participants

HICPAC Members

Dr. Patrick Brennan, Chair
Ms. Vicki Brinsko
Dr. Patchen Dellinger
Dr. Jeffrey Engel
Dr. Steven Gordon
Dr. Lizzie Harrell
Dr. Carol O'Boyle
Dr. David Pegues
Dr. Dennis Perrotta
Ms. Harriett Pitt
Dr. Keith Ramsey
Dr. Nalini Singh
Dr. Philip Smith
Dr. Kurt Stevenson

Designated Federal Official

Dr. Patricia Simone,
Executive Secretary

Liaison and *Ex-Officio* Members

Dr. William Baine (Agency for Healthcare Research and Quality)
Ms. Joan Blanchard (Association of periOperative Registered Nurses)
Ms. Georgia Dash (Association for Professionals in Infection Control and Epidemiology)
Dr. Jeffrey Engel (Advisory Council for the Elimination of Tuberculosis)
Dr. David Henderson (National Institutes of Health)
Dr. Mark Russi (American College of Occupational and Environmental Medicine)
Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)
Dr. Michael Tapper (Society for Healthcare Epidemiology of America)
Dr. Robert Wise (Joint Commission on the Accreditation of Healthcare Organizations)

CDC Representatives

Dr. Denise Cardo, DHQP Director
Dr. Niranjan Bhat
Ms. Elizabeth Bolyard
Ms. Sheryl Gagnon
Dr. Rachel Gorwitz
Ms. Teresa Horan
Dr. John Jereb
Mr. Tony Johnson
Ms. Josephine Jones
Ms. Deborah Levy
Ms. Harriette Lynch
Ms. Michelle Mathieson
Ms. Rosemarie McIntyre
Dr. Priti Patel
Dr. Joseph Perz
Dr. Daniel Pollock
Ms. Cathy Ramadei
Dr. Arjun Srinivasan
Dr. David Weissman

Guest Presenters and Members of the Public

Ms. Kay Argroves (American and Georgia Associations of Nurse Anesthetists)
Ms. Judene Bartley (Association for Professionals in Infection Control and Epidemiology) [via conference call]
Dr. Dale Bratzler (Centers for Medicare and Medicaid Services) [via conference call]
Ms. Gail Bennett (ICP Associates)
Ms. Renee Bryan (Kimberly-Clark)
Ms. Barbara Buchanan (Public)
Ms. Sandy Buhler (Kimberly-Clark)
Ms. Amber Hogan (Becton Dickinson)
Dr. Marguerite Jackson (University of California-San Diego)
Dr. Michele Marill (*Hospital Employee*

Health Newsletter)
Ms. Lisa McGiffert (Consumers Union)
Mr. Girdamo Ortalano
(Pall Corporation)
Dr. Jane Siegel (Texas Southwestern Medical Center)
Ms. Jane Stickel (Becton Dickinson)
Ms. Barbara Waldron (Georgia Association of Nurse Anesthetists)

EXECUTIVE SUMMARY

During the opening session of the meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on October 24-25, 2005 in Atlanta, Georgia, no members declared any new conflicts of interest for the record.

The Centers for Disease Control and Prevention (CDC) provided an overview of the Federal Advisory Committee Act and also played a video on the ethical, conflict of interest and financial disclosure requirements that apply to all federal advisory committee members during their service as special government employees.

The HICPAC Chair described the current national status of public reporting of healthcare associated infections (HAIs). HICPAC unanimously approved a motion to establish a new Public Reporting Workgroup for an initial one-year period. The workgroup will be charged with coordinating, processing and translating information or input on public reporting of HAIs by professional organizations. The workgroup will also make recommendations on the best methods for CDC and the broader community to advance public reporting of HAIs.

The Centers for Medicare and Medicaid Services (CMS) will convene a meeting in November 2005 in an effort to resolve controversies with the Surgical Care Improvement Project (SCIP) measures, particularly routine use of vancomycin, antibiotics for colorectal procedures and existing guidelines on endocarditis prophylaxis. The CDC Division of Healthcare Quality Promotion (DHQP) drafted several recommendations to refine the SCIP measures. A HICPAC member will attend the November 2005 CMS meeting and present DHQP's recommendations at that time. HICPAC and DHQP will convene a conference call to discuss the possibility of forming a new SCIP Measures Workgroup.

Highlights of the current draft of the CMS interpretive guidelines were presented. The document reflects comments previously submitted by the Association for Professionals in Infection Control and Epidemiology (APIC), CDC, HICPAC and other professional societies. However, HICPAC will draft a follow-up letter to CMS to revisit and reinforce issues that were not addressed in its original letter. HICPAC agreed to formally endorse APIC's proposal for CMS to develop education and training standards for surveyors.

Influenza cohorting in long-term care facilities is associated with major theoretical problems, such as the rapid spread of influenza, difficulties in transporting residents and delays in diagnosis. However, cohorting may be the best infection control measure in an extreme situation, such as a novel strain of influenza with no immunity, vaccine or

readily available prophylactic measure. HICPAC will continue to address this issue during future meetings and in the development of new guidelines.

The DHQP Director reported on CDC's new goals management process; the reorganization of the Coordinating Center for Infectious Diseases; personnel changes; the relocation of DHQP to CDC headquarters; the status of the National Healthcare Safety Network; and funding applications submitted for the epidemiological centers. DHQP's efforts to finalize the joint statement on influenza vaccination of healthcare workers (HCWs) by HICPAC and the Advisory Committee on Immunization Practices (ACIP) were delayed to Hurricane Katrina. DHQP will publish the statement in 2006 if the document cannot be finalized in time for the 2005 influenza season.

A writing group of the Infectious Disease Society of America will resolve problems in the current draft of the antimicrobial stewardship (AS) in healthcare guidelines. Education alone may not impact change and should be carefully reconsidered as a primary AS strategy. Antimicrobial cycling is not useful. Existing evidence may not be sufficient to support an A-II rating to recommend electronic medical records and computer physician order entry in an AS strategy. The draft AS guidelines were distributed to HICPAC for review and comment. This item will be placed on a future meeting agenda for HICPAC to determine its role in this effort.

The Food and Drug Administration granted final approval of the QuantiFERON (QFT) Gold TB test in March 2005. Data will continue to be collected to fill several gaps, but nearly all operational problems with the tuberculin skin test will be resolved. Modeling results from cost-effective studies estimate that QFT-Gold will cost $20. CDC is attempting to publish the QFT-Gold guidelines in the *Morbidity and Mortality Weekly Report* (*MMWR*) in February 2006, but is also making efforts to release a web-based version of the document before this time.

CDC reached several conclusions about community-associated methicillin-resistant *Staphylococcus aureus* (CA-MRSA) based on its recent activities of collecting data, investigating outbreaks and conducting studies. MRSA is the most common identifiable cause of purulent skin and soft tissue infections among adult emergency department patients in multiple U.S. cities. MRSA is a cause of post-influenza-like community-acquired pneumonia and other invasive disease in the community. A single strain of MRSA has emerged as a predominant cause of CA-MRSA infection in multiple states.

Methicillin-susceptible *Staphylococcus aureus* that is related to predominant CA-MRSA strains and carries PVL genes contributes to *S. aureus* disease burden in the community. MRSA outbreaks in the community have ended following implementation of

multi-faceted interventions focusing on increased awareness, early detection and appropriate management, enhanced hygiene and maintenance of a clean environment. MRSA with bacteriologic properties of CA-MRSA is being transmitted in healthcare facilities. The increasing prevalence of MRSA in the community presents additional challenges to the control of MRSA in healthcare facilities.

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) clarified the requirements to reduce the risk of HAIs in its 2006 national patient safety goals. However, several topics were excluded from the document pending further research or publication.

HICPAC's liaison members presented reports and distributed written summaries to outline current activities, priorities and future initiatives of the Agency for Healthcare Research and Quality; American College of Occupational and Environmental Medicine; APIC; Association of periOperative Registered Nurses; JCAHO; National Institutes of Health; and Society for Healthcare Epidemiology of America.

HICPAC extensively reviewed and discussed the current draft of the isolation precautions (IP) guideline. All outstanding issues with the exception of one presented by the authors were approved by HICPAC through general agreement, a majority vote or unanimous vote. HICPAC did not approve adding contact isolation precautions to the interim recommendations for infection control in healthcare facilities that care for patients with known or suspected avian influenza.

HICPAC unanimously approved the inclusion of a new recommendation in the IP guideline with a Category IB rating. "Operators should wear surgical masks during myelogram and epidural catheter placement procedures." HICPAC unanimously approved the IP guideline in its entirety. CDC will initiate the *MMWR* clearance and Office of Management and Budget review processes at the same time and expect to publish the document in early 2006.

The National Institute for Occupational Safety and Health will launch the second phase of its National Occupational Research Agenda (NORA) in 2006 with a focus on eight industrial sectors, including healthcare and social assistance. NIOSH will form sector research councils to assist in this effort and convene public town hall meetings throughout the country to obtain input. CDC encouraged HICPAC and other professional groups to provide feedback on NORA to NIOSH.

CDC's recent letter to the subcommittee that is rewriting the United States Pharmacopeia (USP) standards on compounding pharmacies proposed three major

revisions. The standards should include a clear definition of “compounding” and explicitly state that compounding should never be used to bypass drug manufacturing regulations. The use of alcohol-based hand rubs should be specifically recommended. The environmental microbiology sampling recommendations should be reexamined and modified to be consistent with HICPAC guidance. The subcommittee that is rewriting the USP standards will hold a meeting in November 2005. USP will publish the revised standards in the *Federal Register* for public comment.

ACIP is reviewing the literature on pertussis vaccination of HCWs to determine cost, outbreaks and other issues. CDC will distribute a survey to hospitals to determine the institutional burden of pertussis and identify actions facilities are required to take to respond to cases. ACIP will distribute a document on pertussis vaccination of HCWs for review and comment after analyzing results of the CDC survey. HICPAC is encouraged to weigh in on appropriate use of the pertussis vaccine in HCWs prior to the February 2006 ACIP meeting.

The HICPAC Chair, DHQP Director, members and liaisons listed their respective action items. The next three HICPAC meetings will be held on February 9-10, 2006, June 1-2, 2006 and October 23-24, 2006.

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NATIONAL CENTER FOR INFECTIOUS DISEASES
DIVISION OF HEALTHCARE QUALITY PROMOTION

HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
October 24-25, 2005
Atlanta, Georgia

Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Infectious Diseases (NCID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on October 24-25, 2005 at the Sheraton Colony Square Hotel in Atlanta, Georgia.

Opening Session

Dr. Patrick Brennan, the HICPAC Chair, called the meeting to order at 8:40 a.m. on October 24, 2005. He welcomed the attendees to the proceedings and opened the floor for introductions. No HICPAC members declared any new conflicts of interest for the record; the list of participants is appended to the minutes as Attachment 1.

Overview of the Federal Advisory Committee Act (FACA)

Ms. Michelle Mathieson and Ms. Josephine Jones of CDC reported that FACA provides the legal foundation for and formalized the process to establish, operate, oversee and terminate federal advisory committees. A new advisory committee is formed only when the group is determined to be essential. Advisory committees provide federal officials and the nation with relevant and objective guidance that is open and accessible to the public, remains free from undue influence and impacts federal policies and programs.

Each advisory committee operates under standards and uniform procedures and is terminated after its original purpose is fulfilled. The President, Congress, General Services Administration, agency leadership and committee management officers all play a role in overseeing, managing, reviewing and regularly reporting activities of advisory committees. Federal advisory committees may be established by the President, statute or agency discretion. The intent to form an advisory committee is announced in a public notice and memorialized in a charter. A designated federal official (DFO), chair and members are then appointed.

Committee memberships must be fairly balanced in terms of points of view, function and representation. Three types of members may serve on advisory committees. Special government employees (SGEs) are private citizens who are appointed based on expertise in the subject matter and are subject to ethical conduct standards for executive branch employees. *Ex-officio* members are federal officials with expertise in the subject matter who represent their respective agencies. Liaison members represent special interest groups, organizations or affected populations.

Advisory committee meetings must be convened according to FACA requirements, including a public notice in the *Federal Register*, attendance by the DFO, a public comment period, detailed minutes and maintenance of official committee records. Advisory committees may form subcommittees or workgroups to perform special tasks or focus on specific issues. These groups must contain representation of the parent committee and report its findings or recommendations to the parent committee for formal action. Recommendations that are formally approved by an advisory committee through a vote are submitted to the CDC Director and HHS Secretary.

SGEs must comply with several requirements while serving on advisory committees. A financial disclosure report must be completed and submitted upon appointment and annually thereafter. This document protects SGEs and the agency, ensures that activities of the committee will be conducted without actual or perceived conflicts of interest, and allows the agency to determine appropriate actions to take if a conflict arises. SGEs are asked to publicly disclose conflicts of interest and recuse themselves from participating in or voting on any matter that would specifically and directly affect their financial interests.

While performing their official duties, SGEs are prohibited from seeking or accepting any item of value in return for being influenced; receiving compensation for representing an individual or specific issue; acting as an agent or lobbyist on behalf of a foreign entity; and receiving any present, emolument, office or title from a foreign state without the consent of Congress. SGEs must also comply with the post-employment statute

that outlines requirements on representing another individual or entity to the government after the appointment is completed.

CDC played "The Ethical Choice" video for HICPAC to illustrate scenarios related to ethical issues, conflict of interest and financial disclosure that may arise for SGEs. HICPAC members with questions about these issues were advised to contact the CDC Committee Management Office or Dr. Patricia Simone, the HICPAC Executive Secretary.

Update on Public Reporting of Healthcare-Associated Infections (HAIs)

Dr. Brennan covered the following areas in his status report. At this time, seven states have passed laws requiring disclosure of HAIs to the public or the state and an additional six states have pending study bills or resolutions. Key findings from a research brief issued by the Pennsylvania Health Care Cost Containment Council (PHC4) in July 2005 are as follows. Pennsylvania hospitals reported 11,668 HAIs with urinary tract infections (UTIs) accounting for >50%, blood stream infections (BSIs) accounting for 15%-20%, and surgical site infections (SSIs) or pneumonias accounting for 10%-15%. Hospital admissions for these HAIs were associated with 1,793 deaths, 205,000 extra hospital days and an additional $2 billion in hospital charges. Payers in the state estimated that the 11,668 reported HAIs cost ~$340 million.

Of all hospitals in the state, 17% reported 51% of HAIs and 16 reported no infections. PHC4 is extremely interested in a reporting discrepancy between the 11,668 HAIs reported by hospitals and 115,631 infections billed to purchasers. The discordance in reporting was attributed to several factors. Many billing codes did not distinguish between HAIs and community-associated infections (CAIs). PHC4 permitted exceptions to hospital reporting and allowed data to be submitted "as is." Of all hospitals that reported no infections, 50% have verified these data. PHC4 screened 2004 billing data to identify diagnoses that may indicate the presence of an HAI. Coded infections that were not present at admission were inferred to be hospital-acquired.

Several problems were noted with administrative data. HAIs were not precisely identified; no distinction was made in pneumonia codes between HAIs and CAIs; and coding was found to under-represent infections. In one hospital, 17% of coded secondary UTIs were associated with hospital care and 88% of >700 patients coded with UTIs were for events in the first three days of hospitalization. However, these events are unlikely to be related to hospital care. PHC4 is now funding small grants at six hospitals throughout the state to examine the impact of public reporting of HAIs.

At the federal level, the House Energy and Commerce Committee is requesting information from eight large U.S. hospitals on methods that are being used to detect, monitor and report HAI rates. Key questions have been formulated in this effort and will be distributed to the participating hospitals. At the private level, professional organizations are collaborating to jointly address different reporting requirements in multiple states. The National Quality Forum (NQF) is attempting to achieve national consensus on this issue, but the process is now tabled in an effort to leverage $450,000.

The Association for Professionals in Infection Control and Epidemiology (APIC), Infectious Disease Society of America (IDSA), and Society for Healthcare Epidemiology of America (SHEA) are attempting to coordinate this activity, but APIC is the only organization that has pledged funds to date. Dr. Brennan asked the members to consider HICPAC's role in this initiative.

HICPAC noted that eight months have passed since its guidance document on public reporting of HAIs was released. Several members were in favor of HICPAC updating the document on an ongoing basis to reflect the changing environment of public reporting. HICPAC made several suggestions for its continued role in this effort.

- Translate HICPAC's guidance document into actual practice. Formulate specific recommendations on implementing process measures and analyzing data based on different surveillance methodologies. For example, select a limited number of surveillance indicators and stratify recommended methods by hospitals with electronic medical records or data mining systems versus those with simple approaches.
- Use HICPAC's influence and prominence in the infection control community to urge individual institutions and the broader healthcare industry to engage in public reporting of HAIs. Allow sufficient time for concentrated interventions and highlight the benefits of this effort to these groups.
- Compile and widely disseminate successes in public reporting of HAIs instead of allocating additional resources to enhanced surveillance methods.
- Evaluate potential adverse impacts, inequitable effects or unintended consequences of public reporting laws, particularly on minority groups, uninsured persons and other vulnerable populations.
- Review activities in states other than Pennsylvania that serve as better models of public reporting of HAIs and provide more opportunities to

implement systems. For example, laws passed in Illinois, Missouri, New York and Virginia allow for limited indicators and a gradual phase-in of public reporting of HAIs. The Pennsylvania law was passed in response to a "semi-governmental" agency rather than state legislature.

- Clearly describe methods for the broader infection control community to apply various indicators to practice, such as the Centers for Medicare and Medicaid Services (CMS) Surgical Care Improvement Project (SCIP).

Dr. Denise Cardo, the DHQP Director, provided CDC's perspective on opportunities for HICPAC to take a more proactive approach in addressing public reporting of HAIs. First, HICPAC should develop and distribute explicit guidance and standards in the areas of informatics, electronic medical records, national reporting and future research needs. Second, HICPAC should identify, clearly define, and coordinate roles and responsibilities of CDC and other groups in this effort to avoid duplication. For example, CMS and the Agency for Healthcare Research and Quality (AHRQ) could serve as key funding partners on patient safety activities. Third, HICPAC should present current needs in public reporting of HAIs to professional organizations and potential donors to leverage funding.

Dr. Cardo announced that during a series of conference calls, professional organizations and other key stakeholders asked CDC to charge HICPAC with leading a collaborative and coordinated effort to identify priorities in public reporting of HAIs. CDC's position is that HICPAC can take several actions to respond to this request. HICPAC should establish a workgroup with representatives from APIC, IDSA, SHEA, federal agencies and the Council of State and Territorial Epidemiologists (CSTE). The workgroup should be formed with a clear charge and time-line to define broad issues, specify current gaps, identify and assess lessons learned or best practices in existing activities, produce evidence on public reporting of HAIs, and determine future directions.

For example, the workgroup could initially focus on difficulties in collecting BSI data, even with electronic data sources and process measures. The workgroup could develop a document describing methods for CDC, APIC, IDSA and other groups to address this issue. After the workgroup reports its findings to HICPAC, the voting members would take formal action on devising a strategic plan. CDC is concerned that payers may allocate dollars to activities other than public reporting of HAIs if HICPAC does not take a leadership role in this effort.

Dr. Brennan entertained the following motion for HICPAC to continue its role in public reporting of HAIs. HICPAC will establish a workgroup that will initially operate for a one-year period, but will be renewed as necessary. The workgroup will be represented by at

least two HICPAC members and outside experts as needed. The workgroup will serve as a common voice for infection control and will be established with a two-fold charge. First, information or input on public reporting of HAIs by APIC, CSTE, IDSA, SHEA and other groups will be processed, translated and coordinated. Second, recommendations will be made on the best methods for CDC and the broader community to advance public reporting of HAIs. The workgroup's findings will be presented to HICPAC for review, discussion and a formal vote.

The motion was properly moved and seconded by voting members and **unanimously approved** by HICPAC with no further discussion. Drs. Brennan and Cardo will collaborate to solicit members of the new Public Reporting Workgroup from HICPAC and other groups.

Update on the CMS SCIP Measures

Dr. Patchen Dellinger is a HICPAC member and reported that surgical infection prevention began as an explicit CMS priority in 2000 with a goal of reducing SSIs in Medicare patients. CMS convened a national panel with expertise in SSIs and prophylactic antibiotics to assist in this effort. Based on expert guidance from the panel, CMS targeted procedures with two key characteristics. The procedures should be performed on a significant number of Medicare patients. Prophylactic antibiotics should be considered indicated for all of these procedures and should not be controversial.

CMS reviewed and compared guidelines for prophylactic antibiotics published by various professional societies and established several goals. The proportion of patients who had perineal antimicrobial prophylaxis one hour prior to incision or two hours prior to the administration of vancomycin and fluoroquinolones should be measured. The proportion of patients given a prophylactic antimicrobial regimen consistent with published guidelines should be measured. The proportion of patients whose prophylactic antimicrobial agent was discontinued within 24 hours after the end of the operation should be measured. The published guidelines covered cardiac and vascular surgery, hip and knee arthroplasty and colorectal surgery, but the literature did not contain recommendations for hysterectomy patients who are allergic to penicillin or beta-lactam antibiotics.

The review of the published guidelines resulted in two key findings. No data have been produced demonstrating that any drug given after the end of a procedure ever prevented an SSI. Solid evidence has shown that continuing antibiotics increases antimicrobial resistance, but the appropriate length of time to continue these agents is

one of the major differences in the published guidelines. CMS convened a Surgical Infection Prevention Guidelines Workgroup in January 2003 with representation by many professional societies to harmonize the existing recommendations. The workgroup's statement was published in 2004.

In support of the national Surgical Infection Prevention Project (SIPP), CMS surveyed >34,000 Medicare patient records from all 50 states and published the results in 2005. The survey gathered data on current performance among surgeons in administering antibiotics to Medicare patients before and after an operation, using antibiotics consistent with the published guidelines and discontinuing antibiotics. CMS then developed SCIP to address several areas, including SIPP measures on antibiotic prophylaxis; prevention of venous thromboembolism, various cardiac risk factors and post-operative ventilator-associated pneumonias; the time period of 48 hours for cardiac surgery; glucose control in cardiac surgery patients; proper hair removal; and maintenance of normal temperature in colorectal surgery patients.

Several controversies are associated with the SCIP measures. Data have been produced that clearly show vancomycin is an inferior prophylactic antibiotic for methicillin-sensitive infections, but no professional society has issued explicit recommendations to date on appropriate use of vancomycin for "routine prophylaxis." Recommended antibiotics for colorectal procedures are not readily available at this time. Guidelines on endocarditis prophylaxis are inconsistent. CMS will convene a meeting in November 2005 with the guidelines authors in an effort to resolve these controversies. Several items have been placed on the agenda, including a review of indicators, national trends and antibiotic selection; an update of the guidelines comparison document; and discussions on appropriate use of vancomycin for prophylaxis, colorectal operations and endocarditis prophylaxis.

Dr. Dale Bratzler of CMS joined the meeting by conference call and provided additional details on the SCIP measures. Public reporting on the antibiotic selection performance measure has been suspended at this time due to uncertainties about vancomycin use and other issues. However, data are still being collected on this measure. Based on outcomes from the November 2005 meeting, CMS expects to resume public reporting of this measure in July 2006. The Steering Committee of the National Surgical Care Improvement Project identified outcome measures that all hospitals should collect, but acknowledged these measures are not useful for comparisons between institutions or public reporting and are only beneficial for internal quality improvement. Risk-adjusted readmission and mortality rates in Medicare patients are the only two SCIP measures being considered for public reporting.

Dr. Brennan read several recommendations DHQP has drafted to refine the SCIP measures. One, the Department of Veterans Affairs or another federal agency should be urged to fund and support a randomized control trial of vancomycin because data on the relative efficacy of this agent are severely lacking. Two, current published data should be modeled to identify methicillin-resistant *Staphylococcus aureus* (MRSA) incidence rates that would produce better outcomes using vancomycin. Three, a sensitivity analysis should be performed to determine changes in the level of effectiveness. These findings should be used to identify threshold levels of appropriate agents to use.

Four, a determination should be made on whether hospitals participating in SIPP would agree to link process and outcome data to provide a richer source of information, address outstanding issues and fill current gaps. Five, CDC should be encouraged to facilitate a follow-up meeting to discuss existing data sources, including CMS, the National Nosocomial Infections Survey (NNIS) and National Surgical Quality Improvement Program. The meeting should serve as an opportunity to identify strategies to collect additional data and perform new analyses. Six, HICPAC should assist CDC, CMS and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in identifying appropriate outcome data on SSIs to collect in the future.

Dr. Brennan described next steps for HICPAC to strengthen the SCIP measures. "An investigation of the utility of screening patients for either *Staphylococcus* or MRSA colonization" will be added to DHQP's list of recommendations. Dr. Dellinger will represent HICPAC and IDSA at the November 2005 CMS meeting and will present DHQP's recommendations to the guidelines authors at that time. Drs. Brennan and Dellinger will participate in a conference call with DHQP to explore the possibility of forming a new HICPAC SCIP Measures Workgroup.

Update on the CMS Interpretive Guidelines

Ms. Judene Bartley of APIC joined the meeting by conference call and described revisions to the draft interpretive guidelines CMS has made to date based on comments submitted by APIC, CDC, HICPAC and SHEA. Language on "full hospital-wide surveillance" was clarified by defining surveillance as a code term. The interpretive guidelines recommend designing surveillance programs with national guidelines and targeting surveillance rather than implementing "house-", "hospital-" or "system-wide" programs. The guidelines now refer to the "program" as an "infection and prevention

control program." A reference to professional groups was incorporated to substitute the list of guidelines from individual organizations.

"Sentinel event" was deleted because this term is confusing compared to JCAHO language. The quality assurance performance improvement (QAPI) section refers to data collection across all departments rather than the volume of information to report, but this section will be clarified in the next iteration of the guidelines. The sanitation and bioterrorism sections will also be strengthened in the next draft. The phrase "as determined by the facility" was incorporated throughout the document to be consistent with a targeted surveillance program.

The term "infection control professional" (ICP) will be broadened in the next draft to include all infection control staff. The definition of "competency" was changed to education, training "or" certification. Language stating that "an ICP is viewed as qualified if current competency is demonstrated and certification is actively pursued" will be added to the actual surveillance procedures. Paragraphs supporting the need for resource allocation based on the complexity of the hospital and recommendations or studies from APIC, CDC, HICPAC and SHEA were not substantially changed. The term "infection control committee" will be clarified because these groups may be part of a larger quality committee based on the design of the individual institution.

APIC, CDC and HICPAC submitted letters to CMS requesting that the regulation for infection control officers to maintain an incident log of infections and communicable diseases be interpreted as "reportable" diseases. CMS did not accept this request due to the importance of maintaining a single log on all types of infections, including HAIs and reportable diseases. However, CMS has agreed that certain elements in the log referring to employees versus patients can be separated and a sub-log can be maintained for reportable injuries and illnesses among employees. Hospitals can report these data in electronic or paper formats. For consistency with targeted surveillance, the phrase "as identified by the organization" was added to all potential items that may be maintained in the log. CMS will continue to clarify the incident log language.

Ms. Bartley provided additional details on the draft interpretive guidelines in response to HICPAC's specific questions. CMS is exploring the possibility of convening training sessions and regional conferences to develop education and training standards for surveyors. The existing training course for surveyors in the state of Michigan may be reviewed as a model in this effort. CMS will hold a meeting to provide APIC, CDC, HICPAC and SHEA with another opportunity to provide input on the interpretive guidelines. However, representatives from these groups should participate in a

conference call with CMS prior to the meeting to highlight and reinforce the most critical issues.

HICPAC commended Ms. Bartley for her extensive efforts in communicating and collaborating with CMS to ensure that comments from CDC, HICPAC and other professional societies were reflected in the draft interpretive guidelines. HICPAC made two suggestions for CMS to consider while continuing to refine the document. First, the definition of a "qualified ICP" should be expanded to include physicians with infectious disease training. Second, CMS should engage the American College of Occupational and Environmental Medicine (ACOEM) and other occupational safety and health organizations in future discussions to strengthen language on the incident sub-log for employees.

Dr. Brennan described HICPAC's next steps in refining CMS's draft interpretive guidelines. He will draft a follow-up letter to CMS to revisit and reinforce issues that were not addressed in HICPAC's original letter. HICPAC will formally endorse APIC's proposal for CMS to develop education and training standards for surveyors through training sessions, regional conferences and a review of the Michigan training course for surveyors.

Overview of Influenza Cohorting in Long-Term Care Facilities (LTCFs)

Dr. Philip Smith is a HICPAC member and reported that "cohorting" is the practice of grouping together patients infected or colonized with the same infectious agent to confine their care to one area and prevent contact with susceptible patients. Healthcare personnel may be assigned to a cohort of patients during outbreaks to further limit opportunities for transmission. Cohorting has been defined in several guidelines and statements published by CDC, HHS, HICPAC and SHEA. The published literature also contains numerous journal articles on cohorting as an outbreak control measure. These data focus on cohorting of patients with influenza, LTCF residents with influenza-like illness (ILI), and residents and staff on units with known or suspected cases of pandemic influenza.

A study published in 2005 showed that ~40% of LTCFs in Nebraska cohorted MRSA or vancomycin-resistant enterococci colonized residents with those colonized or infected with the same organism. The study demonstrated that cohorting is more practical for MRSA and Salmonella than influenza. Cohorting has long been recommended as an option for influenza in LTCFs and other healthcare facilities, but virtually no data have

been produced on cohorting. Examples or documented reports of successfully using cohorting during an influenza outbreak in LTCFs are also absent from the literature.

On the one hand, major theoretical problems with cohorting in LTCFs include the rapid spread of influenza, difficulties in transporting residents and delays in diagnosis. Confining residents to their rooms, eliminating activities in common areas, administering prophylaxis and vaccinating residents are measures that are more feasible and effective than cohorting, particularly when prophylactic medications are available or a vaccine-susceptible strain of influenza is present. On the other hand, cohorting may be the best infection control measure in an extreme situation, such as a novel strain of influenza with no immunity, vaccine or readily available prophylactic measure.

HICPAC noted that its future guidelines should address two key issues related to influenza cohorting in LTCFs. First, a clear distinction should be made between "segregating" and "cohorting." Segregating groups together all new and existing patients with the same disease, while cohorting prohibits admission of new patients to the same area as existing patients, treats patients within the cohort and releases these persons from the hospital. Second, reports in the literature suggesting that vaccination of healthcare providers has a profound impact on the risk for transmission of influenza in LTCFs should be strongly emphasized.

DHQP Director's Report

Dr. Cardo covered the following items in her update. CDC has initiated a new goals management process in which 21 life stages, preparedness and places goals will be developed for the entire agency. CDC will present the goals to other HHS agencies, JCAHO, federal advisory committees and other partners for review and comment. Objectives and action steps drafted for healthcare settings under the "Healthy Places" goal will be of most relevance to HICPAC. CDC will solicit input from HICPAC on whether the healthcare settings goals are measurable, currently being measured and supported by historical data.

CDC is restructuring the Coordinating Center for Infectious Diseases (CCID). The four reorganized centers will focus on vaccination and respiratory diseases; parasitic diseases, food safety and vector-borne diseases; HIV, STD, hepatitis and tuberculosis; and infection control, preparedness, quarantine and other cross-cutting issues. The reorganization will allow the four CCID centers to jointly address common scientific issues and improve collaborations with partners. The new structure will also give HICPAC an opportunity to provide guidance to divisions other than DHQP. CDC plans

to finalize CCID's new structure and announce directors for the four centers in November 2005.

Dr. Simone was recently appointed as the new Director of the Division of International Health in the Office of Global Health, but she will continue to serve as the HICPAC Executive Secretary until the isolation precautions guideline is complete. Dr. Michael Bell was recently appointed to fill a new position in DHQP as the Associate Director for Infection Control. DHQP will soon move to CDC headquarters on Clifton Road and will convene future HICPAC meetings at this location. DHQP will launch the National Healthcare Safety Network (NHSN) with new healthcare facilities early in 2006 and gather data. A web demonstration of NHSN will be placed on a future HICPAC meeting agenda. CDC received ~40 proposals for its epidemiological centers, but is only able to fund four or five applications. The grantees will focus on the need for more research in this area and identify better strategies for surveillance or prevention.

Draft IDSA Guidelines for Antimicrobial Stewardship (AS) in Healthcare

Dr. Brennan reported that an IDSA writing group convened a meeting in October 2005 to review the most recent draft of the AS guidelines. Comments were previously solicited from the writing group and reviewers. Efforts are underway to obtain endorsement from other professional associations, including the American Society of Hematology, Pediatric Infectious Disease Society and Surgical Infection Society.

Key points in the document of particular interest to HICPAC include the role of education in affecting change and behavior; the need to link the goals of the guidelines to patient outcomes if possible; and the role of computer physician order entry (CPOE) as a tool for patient safety. The recommendations provide guidance on members of the hospital team who should participate in an AS program; relationships between AS programs and committees or other structures within the organization; support of AS programs by hospital administration; elements of an AS strategy; and the importance of electronic medical records and CPOE in a solid AS strategy.

The document lists seven elements to consider, prioritize and incorporate into an AS strategy: education, guidelines and clinical pathways, formulary restriction and pre-authorization, antimicrobial cycling, antimicrobial order forms, combination therapy, streamlining or de-escalation of therapy, and parenteral to oral conversion. The writing group will revisit several of the elements proposed for an AS strategy to resolve the following outstanding issues.

Education alone may not impact change and should be carefully reconsidered as a primary AS strategy. Antimicrobial cycling was not found to be useful because this element only temporarily reduces incidence of a multi-drug resistant organism (MDRO). Existing evidence may not be sufficient to support an A-II rating to recommend electronic medical records and CPOE in an AS strategy. The draft AS guidelines were distributed to HICPAC for review and comment. Dr. Brennan confirmed that AS in healthcare will be placed on a future meeting agenda for HICPAC to determine its role in this effort.

Update on the QuantiFERON (QFT) Gold TB Test

Dr. John Jereb of CDC reported that the Food and Drug Administration (FDA) granted final approval of the test in March 2005. QFT-Gold is a whole-blood test and was approved as an aid in detecting *Mycobacterium tuberculosis* infection either with latent TB infection or TB disease. Use of QFT-Gold requires a fully equipped, capable and trained laboratory. The test must be mixed and ran in the laboratory within 12 hours of drawing a blood specimen. Data will continue to be collected to fill several gaps in QFT-Gold. The efficacy of the test in immunocompromised or immunosuppressed patients and children $\leq$6 years of age is uncertain. Capacity of the test in predicting the potential for TB in the future is unknown.

Hospital infection control and employee health programs are expected to be the largest QFT-Gold users and will benefit from advantages of the test. Nearly all operational problems with the tuberculin skin test will be resolved. Healthcare workers (HCWs) will only be required to make one visit to the employee health program to have blood drawn and will not need to return to obtain test results. The need for two-step testing at induction will be eliminated because QFT-Gold has no potential for boosting. Prior BCG vaccination and most non-tuberculous mycobacteria will not influence test results. Modeling results from cost-effective studies estimate that QFT-Gold will cost $20. CDC is attempting to publish the QFT-Gold guidelines in the *Morbidity and Mortality Weekly Report* (*MMWR*) in February 2006, but is also making efforts to release a web-based version of the document before this time.

Update on Community-Associated MRSA (CA-MRSA)

Dr. Rachel Gorwitz of NCID described CDC's ongoing efforts to address CA-MRSA. Atlanta, Baltimore and Minnesota were the three sites involved in the first phase of MRSA surveillance through the Active Bacterial Core surveillance (ABCs) system in

2001-2002. A total population of >16 million is now covered due to the inclusion of six additional sites in the ABCs system in 2004. Laboratory-based surveillance was conducted for all culture-confirmed MRSA infections during the first phase, including both invasive and non-invasive infections. However, only invasive MRSA infections are tracked through the ABCs system at this time because many sites did not find continued surveillance for all MRSA infections to be practical in the long term.

The current protocol for MRSA surveillance through the ABCs system is as follows. Active laboratory-based surveillance is conducted for MRSA cultures from normally sterile sites. Cultures and patients are identified and medical records are reviewed to determine if the patient has risk factors for a MRSA infection. Infections are categorized as either HAIs or CAIs. Sites submit isolate samples to CDC to characterize and describe the diversity in genotype susceptibility profiles. Preliminary analyses are performed and results are presented at national conferences. Investigators calculate incidence rates by site after a full year of data is available from all sites. Patient interviews to confirm the absence of healthcare risk factors were eliminated from the current protocol because this effort was extremely labor intensive and resulted in the redistribution of cases from community- to healthcare-associated.

A 2005 analysis of community-associated invasive MRSA infections showed an overall proportion of 13.5% among all surveillance sites with a range of 3% in New York to >20% in Maryland. The same analysis examined differences in clinical syndromes between community- and healthcare-associated invasive MRSA infections. The analysis showed that CAIs were less likely than HAIs to present with bacteremia and more likely to present with purulent skin and soft tissue infections, endocarditis, deep-seated abscesses, septic arthritis and metastatic complications. These data suggest that for community-associated MRSA bacteremia, efforts should be made to identify an underlying deep-seated cause of infection.

CDC's EMERGEncy ID Net program is a network of 11 academic emergency departments across the country that are grantees of the Emerging Infections Program. CDC partnered with the network in August 2004 to conduct a one-month study on the etiology of skin infections among adult patients presenting to emergency departments. Across all sites, MRSA was cultured from 59% of skin and soft tissue infections; 17% of cultures grew methicillin-susceptible *Staphylococcus aureus* (MSSA); and Group A streptococcus was rarely cultured. The proportion of skin infections from which MRSA was isolated ranged from 15% in New York City to 74% in Kansas City. MRSA was the most common identifiable cause of skin infections in all but one site.

Most *Staphylococcus aureus* (*S. aureus*) isolates that were submitted to CDC during the network study were of a single pulsed-field type. The USA 300 strain accounted for 97% of MRSA isolates and 31% of MSSA isolates. Of the 218 MRSA isolates, 72% were caused by a unique indistinguishable pulse-field pattern that has been associated with outbreaks in many states. Of the patients with MRSA infection, >25% had healthcare risk factors that would have been characterized as HAIs as defined by the ABCs system. Nearly all of the isolates were pulse-field types associated with community disease.

A 2004 study of *S. aureus* community-acquired pneumonia following ILI during the 2003-2004 influenza season showed that 15 of 17 cases reported to CDC were due to MRSA, but only 24% had MRSA risk factors. The median age of the patients was 21 years with a range of 8 months to 62 years. Of the 17 cases, 29% had an underlying disease, 71% had laboratory confirmation of preceding influenza illness, 94% were hospitalized, 81% were placed in the intensive care unit (ICU) and 29% died. Of 10 isolates that were available for characterization by CDC, 8 from six states had a unique indistinguishable pulse-field pattern. The study demonstrated that MRSA can be a cause for community-acquired pneumonia. CDC is partnering with the EMERGEncy ID Net grantees to conduct a study on the etiology of community-acquired pneumonia and further describe the role of *S. aureus* as a risk factor.

A 2004 study on *S. aureus* colonization was based on data from ~5,000 nasal swabs collected and cultured each year during the 2001-2002 National Health And Nutrition Examination Survey (NHANES) nasal swab survey. The study showed a 32% prevalence of *S. aureus* nasal colonization with a peak in children 6-11 years of age and a strong relationship to males and non-Hispanic whites. Nasal colonization with MRSA was 0.8% with a strong relationship to females and persons >60 years of age. The lack of association with recent healthcare exposure may be attributable to insufficient study power. CDC is continuing to collect data from the 2002-2003 NHANES nasal swab survey to determine if the prevalence of nasal colonization with MRSA is increasing.

CDC and the Minnesota Department of Health are conducting a study on household transmission of CA-MRSA. Pediatric patients with CA-MRSA are being identified through routine surveillance and will be enrolled in the study along with household members. Three visits will be made to each home to obtain nasal swabs from household members, collect data on infection history, and gather information on behaviors or exposures that may be related to MRSA transmission. Efforts will be made to enroll classmates of index cases in day care centers, conduct a one-time nasal swab survey of these children, and obtain information on practices in the day care center that may be related to MRSA transmission.

The study is designed with a two-year data collection period and a key outcome of describing the extent to which nasal colonization and infections occur in households where CA-MRSA cases have occurred. Another component for household pets will be added in year 2 of the study due to data that show a relationship between companion animals and colonization and infection with MRSA.

CDC is investigating and will publish reports of MRSA skin infections in new settings, including a closed religious community, residents in a rural Georgia community, tattoo recipients and hurricane evacuees. The outbreaks were associated with several risk factors for CA-MRSA transmission, such as crowded areas, frequent contact, contaminated surfaces and shared items, compromised skin, lack of cleanliness, antibiotic exposure and limited access to healthcare. The literature contains reports of hospital transmission of CA-MRSA among postpartum women in New York, a neonatal ICU in Texas, and a hospital nursery and maternity units in New York.

CDC is preparing an *MMWR* article on CA-MRSA outbreaks among healthy full-term newborns. MRSA skin infections were transmitted to newborns delivered at a common facility, but no likely source of acquisition was identified post-discharge. All of the outbreaks were resolved after reinforcement of hand hygiene and other nursery infection control practices and decolonization of colonized HCWs in some cases.

CDC investigated infections caused by CA-MRSA among patients in one hospital in Uruguay in 2002-2004. MRSA isolates were categorized as either community- or hospital-associated based on susceptibility profiles of the patients. The number of infections caused by MRSA increased over time with the non-multi-resistant community-associated susceptibility pattern and decreased over time with the multi-resistant healthcare-associated susceptibility pattern. Of patients with the community-associated susceptibility pattern, ~20% had an onset of symptoms in the hospital. CDC analyzed NNIS data in 2004 to identify isolated resistance to erythromycin in MRSA nosocomial infections among U.S. ICU patients from 1992-2003. The study showed that the percent of isolates with this resistance pattern increased from 4% in 1992 to ~14% in 2002.

CDC reached several conclusions based on its investigations and data reviews. MRSA is the most common identifiable cause of purulent skin and soft tissue infections among adult emergency department patients in multiple U.S. cities. MRSA is a cause of post-ILI community-acquired pneumonia and other invasive disease in the community. A single strain of MRSA has emerged as a predominant cause of CA-MRSA infection in

multiple states. MSSA that is related to predominant CA-MRSA strains and carries PVL genes contributes to *S. aureus* disease burden in the community.

MRSA outbreaks in the community have ended following implementation of multi-faceted interventions focusing on increased awareness, early detection and appropriate management, enhanced hygiene and maintenance of a clean environment. MRSA with bacteriologic properties of CA-MRSA is being transmitted in healthcare facilities. The increasing prevalence of MRSA in the community presents additional challenges to the control of MRSA in healthcare facilities.

Dr. Cardo added that CDC has been criticized for not developing an epidemiological definition of "CA-MRSA." CDC is shifting its focus from distinguishing between "CA-MRSA" and "HA-MRSA" and is attempting to define all infections as "MRSA." CDC is engaging in dialogue with several groups to identify the best strategies for clinicians to characterize skin and soft tissue infections.

HICPAC made two suggestions for CDC to consider in its ongoing efforts to address CA-MRSA. First, 2004 and 2005 laboratory data should be reviewed to determine the actual percentage of clindamycin-susceptible isolates. CDC's study on isolated resistance to erythromycin in MRSA nosocomial infections among ICU patients was based on susceptibility testing performed by hospitals rather than laboratory data. However, more definitive guidelines and tests for laboratories to report clindamycin if erythromycin is resistant have been developed since that time. Second, findings from CDC's CA-MRSA Workgroup meeting that was held in July 2004 should be published due to solid literature reviews by FDA and other groups.

Overview of JCAHO's 2006 National Patient Safety Goals (NPSGs)

Dr. Robert Wise is the ACCLPP liaison member for JCAHO and reported that JCAHO established its sentinel event policy in January 1996 with several goals to review unexpected events causing a serious injury or death. Of 3,231 sentinel events reviewed by JCAHO from January 1995-April 2005, 61 were infection related. However, JCAHO acknowledges a bias in these data due to severe under-reporting. An analysis showed that communication, orientation or training and patient assessment were the top three root causes of sentinel events in all categories from 1995-2005.

JCAHO issues sentinel event alerts to notify the community about serious injuries or deaths associated with certain practices. The alerts have covered issues related to potassium chloride, nosocomial infections and wrong-site surgeries. JCAHO held a

national summit in May 2003 with >30 organizations to address concerns about wrong-site surgeries. Sentinel event trends have worsened since the alert on wrong-site surgeries was issued in August 1998. JCAHO added HAIs to the NPSGs in 2004.

Data collected in 2003-2005 showed that organizations had the highest level of non-compliance to the NPSGs in the areas of standardized abbreviations, time out before surgery, preoperative ventilation, surgical site marketing and CDC's hand hygiene guidelines. Organizations have an opportunity to ask for an alternative approach to the NPSGs. CDC's hand hygiene guidelines represent the single highest request for an alternative method.

Goal 7 of the NPSGs is to reduce the risk of HAIs. The requirement to "manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with an HAI" has been the most resisted, debated and misunderstood goal of all NPSGs. JCAHO added the term "even if" associated with an HAI to minimize confusion and underscore the following points to organizations. The language on HAIs and sentinel events is not a new requirement, but emphasizes that any unanticipated death or major injury is a sentinel event in the presence or absence of an infection. Changes in surveillance methods are not required. The language does not replace traditional rate-based analysis of HAIs. A root cause analysis is a comprehensive examination of the care of the patient along with the infection and is only required for HAIs that result in death or major injury.

JCAHO did not incorporate several topics in the 2006 NPSGs pending further research or publication, including a safety culture, HCW fatigue, technological support for patient identification, elopement, specific high-alert medications, and early recognition and response to failing patients. JCAHO is considering a number of issues to include in the 2007 or 2008 NPSGs, such as a comprehensive risk assessment, management of disruptive behavior, orientation and training of contract workers, anticoagulant management and intravascular catheter infections. JCAHO is also exploring the possibility of expanding the scope of existing requirements for pressure ulcer prevention, patient involvement and surgical fires.

Liaison Reports

Dr. William Baine provided HICPAC with a list of infection control guidelines that are posted on or were withdrawn from AHRQ's National Guideline Clearinghouse (NGC). The guidelines on catheter-associated UTIs were never posted on the NGC, but an opportunity is now available to incorporate this document in light of HICPAC's current

efforts to publish the isolation precautions guideline. AHRQ requires guidelines posted on the NGC to be updated every five years or the organization promulgating the guidelines must provide written assurance that no changes are necessary based on a literature review.

The Patient Safety and Quality Improvement Act of 2005 was recently signed into law to provide for the improvement of patient safety and reduce the incidence of events that adversely affect patient safety. AHRQ's role in the new law will primarily focus on fostering an operational program of patient safety organizations, creating an operational network of patient safety databases, and developing an infrastructure to manage the program. An overview of the new law was distributed HICPAC that described the purpose, major provisions, goals, principal implementation strategies, supporting activities and next steps.

Dr. Mark Russi reported that ACOEM issued a position statement on influenza vaccination of HCWs. The statement strongly supported aggressive actions to make vaccine more easily available to HCWs through off-site and off-shift clinics, vaccine fairs, educational campaigns and other strategies with demonstrated success in vaccination of HCWs. The statement did not endorse mandatory vaccination or collection of declination signatures because resources directed to this effort could have a greater impact in bolstering education and increasing availability of the vaccine.

Ms. Joan Blanchard reported that the Association of periOperative Registered Nurses (AORN) is developing guidelines for avian influenza, severe acute respiratory syndrome (SARS) and human influenza. The recommendations are being designed to provide AORN members with a plan for self-care and patient care in peri-operative departments. AORN recently convened the Emergency Management Educational Conference to urge members to consider their potential role in an emergency. AORN and several other groups at federal, state and local levels recently completed a National Disaster Medical System exercise in which 100 patients were transferred from Utah to Colorado for long-term care.

Ms. Georgia Dash reported that APIC is continuing to collaborate with SHEA and other stakeholders to raise $450,000 NQF needs to develop a national standard to collect and report HAIs. APIC contributed $25,000 to NQF to support this initiative. APIC partnered with Trust for America's Health to conduct a "Ready or Not Report Card" survey to identify indicators of hospital emergency preparedness. An analysis of the survey results is expected to be completed in October 2005. APIC submitted a letter to CMS endorsing the proposed rule that would require annual influenza vaccination and

pneumonia vaccination of LTCF residents. APIC is considering the possibility of endorsing mandatory influenza vaccination of HCWs who provide direct patient care.

Dr. Brennan reported that the NCID Board of Scientific Counselors has not held a meeting since the June 2005 HICPAC meeting.

Dr. Wise reported that JCAHO has held initial discussions about influenza vaccination of HCWs with its Professional and Technical Advisory Committees. Based on outcomes from a field review of this issue, JCAHO will develop standards in the spring of 2006 and formally adopt these requirements in time for the 2007 influenza season. JCAHO is continuing to address its limited capacity in determining whether organizations are meeting infection control standards. JCAHO is administering onsite surveys to strengthen its ability in identifying issues and understanding the systems approach to infection control used by hospitals and other organizations. HICPAC can assist JCAHO in this effort by describing effective strategies to rapidly determine organizational compliance with the infection control standards.

Dr. David Henderson provided HICPAC with a written summary of recent activities the National Institutes of Health is conducting to support infection control issues. These efforts include the national response to Hurricanes Katrina and Rita; responses to avian and pandemic influenza; development of the U.S. Public Health Services infection control guidelines; and continued support to develop and implement an epidemiologically-based patient safety and clinical quality program.

Dr. Michael Tapper reported that SHEA has posted a paper on its web site by the Board Commission of Physicians calling for mandatory declination in influenza vaccination of HCWs. SHEA and IDSA will jointly publish a document on stockpiling antiviral drugs, particularly those that are useful for pandemic influenza. The SHEA/CDC infection control training course was recently completed. Under a CDC cooperative agreement, SHEA and APIC will perform additional assessments to improve the provision of information on infection control emergencies to CDC and other partners. This initiative is expected to result in a solid model for SHEA, APIC and CDC to respond to public health emergencies. SHEA's Public Policy Committee is convening monthly conference calls with partners to discuss issues of mutual interest to all groups.

Dr. Cardo reported that DHQP's efforts to finalize the joint statement on influenza vaccination of HCWs by HICPAC and the Advisory Committee on Immunization Practices (ACIP) were delayed to Hurricane Katrina. DHQP will publish the statement in 2006 if the document cannot be finalized in time for the 2005 influenza season.

With no further discussion or business brought before HICPAC, Dr. Brennan recessed the meeting at 4:57 p.m. on October 24, 2005.

Review of the Draft Guideline for Isolation Precautions (IP)

Dr. Brennan reconvened the HICPAC meeting at 8:41 a.m. on October 25, 2005 and announced that the entire morning session would be devoted to an extensive review and discussion of the IP guideline for HICPAC to resolve outstanding issues and formally approve the document. During a recent conference call, HICPAC agreed that the influenza section should provide guidance on standard and droplet precautions. However, the issue of contact isolation was not resolved due to a vote of six HICPAC members in favor of the language and seven opposed. Dr. Brennan planned to call for another vote on contact isolation.

Drs. Cardo and Niranjan Bhat of the NCID Influenza Branch provided additional details about the IP guideline. Ms. Linda Chiarello is serving as a consultant to HICPAC in this effort and drafted interim recommendations on droplet and standard precautions after the last conference call. CDC revised the document to include more information on contact transmission of avian influenza based on recent articles published in the literature. The Influenza Branch considers contact isolation precautions to be a reasonable addition to the IP guideline. CDC has informed HICPAC of its interest in removing airborne precautions from the influenza section.

HICPAC suggested the following revisions to the interim recommendations. The language on standard precautions should be clarified. "Known or suspected avian influenza" should be changed to "known avian influenza." Bullet 2 in the hand hygiene section should be changed to "hand-washing or disinfection." HICPAC was unable to reach agreement on contact isolation precautions during its discussion of this issue.

Dr. Brennan closed the discussion and entertained a motion to add contact isolation precautions to the interim recommendations for infection control in healthcare facilities that care for patients with known or suspected avian influenza. **The motion did not pass with a vote of 4 HICPAC members in favor of the language and 10 opposed**.

Dr. Marguerite Jackson, of the University of California-San Diego, and Dr. Jane Siegel, of Texas Southwestern Medical Center, serve as the primary authors of the IP guideline and presented outstanding issues for HICPAC to resolve in finalizing the document.

HICPAC's responses to the authors on the outstanding issues are outlined below. HICPAC reached general agreement with no objections or abstentions in all areas except where otherwise indicated.

- Retain the language on MSSA.
- Retain the language on common and uncommon microorganisms, but obtain editorial changes from Dr. O'Boyle.
- Add Legionella as an example of Group A streptococcus.
- Retain the "MDRO" definition, but provide additional language to clarify that no true definition has been established for MDROs.
- Retain the background section on Clostridium difficile (C. difficile). However, ensure that the language is consistent with CDC's hand hygiene guidelines. Clearly state that "resolution of diarrhea" is included in the duration of illness for C. difficile.
- Change page 38, line 2 to "bleach-containing disinfectant for environmental cleaning."
- Retain the language on norovirus on page 183. **[7 in favor, 6 opposed, 1 abstained]**
- Retain the language on the eight safe injection practices with the following exceptions. For "use single-dose vials for parenteral medications when possible," add a reference, change the term to "whenever possible" and change the rating to Category IB. Include language in this section on needle-less devices that are used to access multi-dose vials.
- Ensure that the language on patient care environment on page 117 is consistent with the environmental guideline.
- Remove all references to the sterilization and disinfection guideline because the status of this document is unknown at this time.
- Include the use of a dishwasher as an option to clean and disinfect toys.
- Include introductory language on cleaning and disinfecting computers and other multi-use electronic equipment.
- Include the new hand hygiene recommendation proposed by the authors pending review and comments from Dr. John Boyce and Ms. Elaine Larson, who served as expert reviewers for the hand hygiene section. However, change "preferred" to "the advantage of anti-microbial soap." **[12 in favor, 2 opposed]**
- Add language in the background section about hand-held pressure gauges, but do not include a recommendation on this issue for consistency with the TB guidelines.
- Rate the recommendation on the number of airborne isolation infection rooms as Category IC.

- Revise the criteria for discontinuing airborne precautions in Appendix A to be consistent with the TB guidelines.
- Retain the new format for Table 3.

Precautions for Myelograms

Dr. Arjun Srinivasan of DHQP described a case series of post-myelogram streptococcal meningitis. A physician underwent a myelogram procedure and was readmitted to the hospital within 24 hours with bacterial meningitis. The blood cultures grew a streptococcal species. After CDC posted a summary of two cases of post-myelogram streptococcal meningitis on the Emerging Infections Network, five additional cases were reported. All seven cases were extremely ill upon admission and four were obtunded, but all seven patients survived.

CDC's initial investigation revealed that the seven cases occurred in different states. All patients had the same brand of contrast material and the streptococcal species, but of different varieties. Cultures of the contrast material were negative. CDC interviewed radiologists and ICPs for each case and was informed that infection control practices were followed in each institution, but face masks were not worn during the myelograms. CDC reviewed the literature and found three published reports of droplet transmission during myelograms. The infectious disease literature also contains a published debate on the advantages and disadvantages of using face masks for myelograms and other spinal procedures.

The two sides of the debate are as follows. On the one hand, streptococci are the single most common cause of post-myelography meningitis based on reported incidence. Several clusters of cases have been associated with a single operator. Surgical masks for these procedures are relatively inexpensive and not overly burdensome. A survey showed that 50% of obstetrician anesthesiologists use surgical face masks when inserting spinal epidural catheters. Infections from myelograms can be life threatening. Surgical masks and other heightened precautions while inserting central lines have been effective in reducing the incidence of infection.

On the other hand, post-myelogram infections may be due to poor overall techniques. Data are insufficient to demonstrate that masks reduce respiratory shedding of streptococci. Because infections from myelograms are relatively uncommon, the use of masks during these procedures may not be cost effective. However, opponents of face masks point out that masks should be worn in certain circumstances, such as an operator with a respiratory infection, insertion of a device that will remain in place for a

period of time, the need to frequently talk to the patient during a procedure and lengthy procedures.

CDC is now asking HICPAC to include a recommendation in the IP guideline for operators to wear surgical masks during myelogram procedures. CDC is also requesting that the recommendation be rated as Category IB due to supporting data from four epidemiological studies, case investigations and a strong theoretical rationale. The new recommendation would be placed in the safe injection practices section. CDC is attempting to publish the case series in a radiology journal to reach the appropriate target audience.

Dr. Brennan entertained a motion to include a recommendation in the IP guideline as amended by HICPAC based on the discussion. "Operators should wear surgical masks during myelogram and epidural catheter placement procedures." The recommendation should be rated as Category IB. **The motion passed by a unanimous vote**.

HICPAC noted that the new recommendation encourages the use of surgical masks during the placement of epidural catheters. As a result, CDC should also publish the case series in the *MMWR* and anesthesiology journals to reach anesthesiologists.

Review of the Draft Guideline for Isolation Precautions [continued]

HICPAC's responses to the authors on additional outstanding issues are outlined below. HICPAC reached general agreement with no objections or abstentions in all areas except where otherwise indicated.

- Include language to consider TB and clarify that avian influenza does not mean airborne precautions.
- Add a separate line for ILI to the respiratory infection table and recommend droplet and standard precautions. **[10 in favor, 4 opposed]**
- Change page 79, lines 13-16 to "a disposable particulate respirator instead of a surgical mask should be used when the aerosol is likely to contain the SARS virus, variola, avian influenza and hemorraghic fever."
- Retain the Category IB ratings in the administrative responsibilities section on pages 103-108. However, review the current CMS requirements to change the ratings to "Category IB/IC" where applicable and add citations where appropriate.

- Retain the Category IB ratings in the education section on pages 108-109, but describe approaches for hospitals to evaluate the competency of contract staff.
- Retain the Category IB ratings in the surveillance section on pages 109-110, but change “revise” to “review and update for the purpose of developing an action plan” on page 110, line 12.
- Retain the Category IB ratings in the standard precautions section on pages 110-120. However, review data by the National Institute for Occupational Safety and Health (NIOSH) to confirm the strength of the evidence for the standards precautions language on page 74, line 30. Add language about masks with attached face shields and remove the N95 language on page 114, lines 26-28. Change the language for influenza and hemorraghic fever virus in the standard precautions section, add the appropriate citations and provide a Category II rating for the recommendation.
- Retain the Category IA rating in the transmission-based precautions section on page 120, line 18.
- Change page 121, line 2 to “in acute and long-term care facilities.”
- Include language from CDC’s web-based document on influenza in LTCFs on page 122, line 6.
- Add language on aerosol-generating procedures on page 129, line 8 and cross-reference the background section on aerosolization.
- Ensure that the language on “draining TB skin lesions” is consistent with the TB guidelines.
- Obtain confirmation from Dr. Pegues that “at least 12 air changes per hour” is correct on page 132.
- Make the following changes to the judicious use of antimicrobial agents section on page 137. Include “hospitals” in item 2. Change “assure” to “encourage” on line 6 because hospitals cannot ensure that physicians always prescribe the appropriate antibiotics.
- Consult with Dr. Pegues to clarify and strengthen the MDRO section on pages 135-157.
- Consult with Dr. Smith to refine the LTCF subsections on page 144 with the following language. “Adapt contact precautions to LTCF settings considering the risk for transmission, uncontrolled secretions, stool incontinence, draining wounds, diarrhea, total dependence of activities, daily living and resident quality of life issues. Modify contact precautions to allow MDRO patients whose site of colonization or infection can be appropriately contained. Observe good hand hygiene practices to enter common areas and participate in group activities.”

- Determine whether “evidence of transmission” should be more explicitly stated in the indications for intensifying MDRO control efforts on page 147.
- Include language on page 150 to advise facilities to incorporate protocols other than control charts when additional screening is performed or other surveillance techniques change.
- Retain Appendix A as modified by the authors following HICPAC’s conference calls.

Dr. Brennan entertained a motion to approve the IP guideline in its entirety pending the revisions suggested by HICPAC during the meeting, additional references and editorial changes. **The motion passed with a unanimous vote**.

Dr. Simone described next steps in finalizing and publishing the IP guideline. The authors will incorporate comments HICPAC made during the meeting and DHQP will circulate the final revised draft to HICPAC for review. CDC will initiate the *MMWR* clearance and Office of Management and Budget (OMB) review processes at the same time and expect to publish the document in early 2006.

Update on the National Occupational Research Agenda (NORA)

Dr. David Weissman of NIOSH reported that NIOSH is a CDC institute under HHS and is responsible for conducting research and making recommendations on the prevention of work-related injury and illness. The Occupational Safety and Health Act of 1970 established both NIOSH and the Occupational Safety and Health Administration (OSHA), but the two agencies are distinct and separate. NIOSH was formed with three strategic goals. Research is conducted to reduce work-related illnesses and injuries. Safe and healthy workplaces are promoted through interventions, recommendations and capacity building. Global workplace safety and health are enhanced through international collaborations.

NIOSH’s research divisions and laboratories focus on applied research and technology, respiratory disease studies, safety research, education and information, health effects, personal protective technologies, and surveillance, hazard evaluations and field studies. NIOSH’s service activities and programs include health hazard evaluation and technical assistance; fatality assessment and control evaluation; respirator certification; education and research; extramural grants; and information dissemination. NIOSH developed NORA with four overarching goals. An occupational disease research agenda was developed for the nation. Input from stakeholders is solicited to identify research

priorities for the nation. Collaborations are built to address priorities. Funds are leveraged to support research in priority areas.

The ten-year period of 1996-2006 was established as the first phase of NORA. NIOSH convened several stakeholder meetings in 1996 that resulted in the development of 21 priority areas. In the second phase of NORA beginning in 2006, NIOSH will create research agendas that focus on eight industrial sectors, including healthcare and social assistance. NIOSH will also form sector research councils (SRCs) with a specific mission to assist in this effort. A sector-specific research strategy for the nation will be developed and maintained to address the most important problems. The impact of NORA will be maximized through partnerships to promote widespread adoption of improved workplace practices based on research results. A transparent process and stakeholder representation and participation will serve as the guiding principles of the SRCs.

Each SRC will have a diverse membership of employers, labor representatives, academic institutions, trade and professional associations, federal and state partners, practitioners, scientists, occupational safety and health professionals, and NIOSH staff. The SRCs will conduct several activities. Strategic goals will be developed to eliminate the worst problems in the industrial sector. Needs, gaps and barriers will be analyzed. Intermediate goals and outcome measures will be created. Plans will be designed to assure funds, conduct research and adopt successful strategies for prevention through partnerships.

NIOSH will launch the second phase of NORA by convening public town hall meetings in 2005-2006 across the country. Each meeting will be structured with discussions on both regional and industrial sector-specific issues, such as major problems, key partnerships, relevant research and cross-sector research. NIOSH has tentatively scheduled the healthcare and social assistance sector meeting in January 2006 in Albuquerque, New Mexico. HICPAC, other professional groups and the public can also provide input on NORA through an electronic docket on the NIOSH web site or direct e-mail messages to Dr. Weissman.

Dr. Cardo raised the possibility of HICPAC collaborating with the Advisory Council for the Elimination of Tuberculosis to ensure the infection control community is represented on the healthcare sector SRC. This partnership may advance efforts to fill existing data gaps in respiratory protection, TB, sharps injury prevention and other environmental issues. She also encouraged ACOEM, APIC, SHEA and other professional societies to provide NIOSH with input on NORA.

Overview of Compounding Pharmacies

Dr. Srinivasan described CDC's current activities to address issues related to compounding pharmacies. CDC is participating in several outbreak investigations of contaminated products prepared by compounding pharmacies. Some of the outbreaks are associated with large numbers of patients and serious clinical outcomes. FDA defines "compounding" as combining, mixing or altering ingredients to create a customized medication for an individual patient in response to a prescription by a licensed practitioner.

FDA clearly distinguishes between "pharmacy compounding" and "drug manufacturing." Compounded products are not required to adhere to stringent regulations established for manufactured drugs, such as pre- and post-market testing standards, good manufacturing practices, process control measures and sterility testing. However, FDA acknowledges that compounded products can still fill voids and play an important role in the therapeutic armamentarium. Compounding occurs in all areas of the healthcare system. Nearly all acute care hospital pharmacies, several free-standing pharmacies and some clinician offices have a compounding process, such as making custom intravenous solutions.

Current estimates show that compounded products represent ~1% of all prescriptions filled in the United States each year. Based on 2003 data, 30 million products are compounded each year in the country. Assuring the quality and safety of compounded products is difficult due to variations in practice, skills, expertise and equipment. FDA conducted a study in 2001 in which 29 products were randomly mail ordered from different compounding pharmacies and tested with the rigorous drug manufacturing process. Of the 29 products, 34% failed one or more of the quality tests. The failure rate was found to be significant compared to the rate of <2% for manufactured products. Another major concern is that compounding pharmacies are actually manufacturing products under the less stringent compounding process.

Compounded medications fall under FDA's regulatory authority granted by Congress, but FDA exempts legitimate compounding from the strict manufacturing standards. Compounding pharmacies urged FDA to issue a formal codification outlining the role of the federal government in regulating these facilities. The FDA Modernization Act that was passed by Congress in 1997 restricted the ability of compounding pharmacies to advertise and solicit prescriptions. The U.S. Supreme Court agreed with a lawsuit filed by compounding pharmacies that the new law violated rights to commercial free speech and overturned the law in 2002.

Written laws on regulating compounding pharmacies are now only maintained at the state level and significantly differ among states. FDA recently issued guidance to address this problem. Regulations will be enforced on compounding pharmacies that appear to be actually manufacturing products, such as those compounding large quantities of drugs with no prescriptions on hand, distributing a tremendous amount of products to other states or using commercial scale equipment.

The U.S. Pharmacopeia (USP) and the National Formulary issued standards in 2004 that govern pharmaceutical compounding of sterile preparations. The document is considered to be required and enforceable by FDA, state pharmacy boards and accreditation organizations. CDC's position is that the USP standards are solid overall and will assist in improving the safety of compounded medications. However, CDC is concerned with some of the standards from a healthcare epidemiology perspective, particularly those related to environmental microbiology.

CDC noted problems with the USP standards in the areas of routine air culturing, surface sampling and hand culturing. The environmental microbiology standards recommend that compounding pharmacies take certain actions for sampling, but the thresholds are arbitrary and not based on experiences with adverse outcomes. Environmental sampling conducted by hospital-based compounding pharmacies will create different standards than operating rooms and other high-risk areas of the institution. Routine environmental sampling produces extremely variable results even under fairly controlled circumstances.

CDC concluded that the USP standards on routine and environmental cultures directly contradict HICPAC's recommendations in the environmental infection control guideline. However, an opportunity currently exists to address this problem because the USP standards are now being revised. CDC recently submitted a letter to the subcommittee that is rewriting the USP standards and proposed three major revisions.

First, the standards should include a clear definition of "compounding" and explicitly state that compounding should never be used to bypass drug manufacturing regulations. Second, the use of alcohol-based hand rubs should be specifically recommended. Third, the environmental microbiology sampling recommendations should be reexamined and modified to be consistent with HICPAC guidance. The subcommittee that is rewriting the USP standards will hold a meeting in November 2005. USP will publish the revised standards in the *Federal Register* for public comment. CDC will continue to engage USP in revising the standards; educate clinicians about compounding pharmacy issues; and provide HICPAC with its letter to USP and those from other groups.

Update on Pertussis Vaccination of HCWs

Dr. Steven Gordon is a HICPAC member and reported that ACIP is attempting to provide evidence-based guidance on primary immunity protection for HCWs. ACIP is reviewing the literature on pertussis vaccination of HCWs to determine cost, outbreaks and other issues, but the case reports are biased, passive and primarily limited to Massachusetts.

Key findings from reports documented in the literature are as follows. The burden of pertussis among HCWs by exposure or lack of immunity is estimated to be two times higher than the general population. Transmission may result in morbidity and several different transmission patterns have been detected. Both direct and indirect costs for prevention control measures may be substantial in terms of lost work days and post-exposure prophylaxis. Pertussis in HCWs is most common among those who care for pediatric patients, but outbreaks have also been documented in teaching hospitals that provide pediatric and obstetrician services.

Recommendations at the global level include universal pertussis vaccination of adults in Canada; HCWs and child care workers with face-to-face contact with infants <3 months of age in Australia; and persons at occupational risk by the Global Pertussis Initiative. Administration of pertussis vaccine to the appropriate HCWs and settings is still uncertain. CDC will distribute a survey to hospitals to determine the institutional burden of pertussis and identify actions facilities are required to take to respond to cases. ACIP will distribute a document on pertussis vaccination of HCWs for review and comment after analyzing results of the CDC survey. HICPAC is encouraged to weigh in on appropriate use of the pertussis vaccine in HCWs prior to the February 2006 ACIP meeting.

HICPAC Business

Dr. Brennan will take the following actions. Members will be solicited, conference calls will be held with professional groups and other efforts will be made to initiate activities for HICPAC's new Public Reporting Workgroup. A conference call will be held with Dr. Dellinger and DHQP to coordinate HICPAC's new SCIP Measures Workgroup. A conference call will be held with the Surveillance Workgroup to shift the focus of this effort to informatics. A conference call will be held with DHQP to structure the next meeting agenda around the role of informatics in public reporting and other infection control issues.

Dr. Cardo will take the following actions. The OMB clearance process will be expedited for HICPAC's IP and disinfection and sterilization guidelines. HICPAC's liaison members for ACOEM, APIC and SHEA will be asked to assist in identifying an expert from each organization who will review the IP guideline in accordance with OMB requirements. A web demonstration of NHSN will be placed on the next HICPAC meeting agenda. Letters from CDC and other groups to USP on the compounding pharmacy standards will be distributed to HICPAC for review. The status of CDC's survey to hospitals on the institutional burden of pertussis will be reported to HICPAC. The final ACIP/HICPAC joint statement on influenza vaccination of HCWs will be circulated to HICPAC.

HICPAC members and liaisons will continue to participate in activities of existing workgroups, volunteer to serve on new workgroups, and submit written comments to the authors of the IP guideline.

Closing Session

The next three HICPAC meetings will be held on February 9-10, 2006, June 1-2, 2006 and October 23-24, 2006. With no further discussion or business brought before HICPAC, Dr. Cardo adjourned the meeting at 2:05 p.m. on October 25, 2005.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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Patrick J. Brennan, M.D.
HICPAC Chair